REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the following remarks.

STATUS OF CLAIMS

Claims 1-11, 28-35, 46-51 and 53 are now in this application. Claims 36 and 52 have been cancelled by the foregoing amendment, without prejudice or disclaimer. Claims 12-27 and 37-45 were previously cancelled. Claim 53 has been added.

DRAWINGS

Applicants note, with appreciation, that the drawings have been accepted.

PRIORITY UNDER 35 U.S.C. § 119

The acknowledgment of the claim for foreign priority is noted. The Examiner has indicated that a certified copy of the priority documents has been received. However, as this was a national stage application, in fact a copy of the certified copy of the priority document (FR 02 08613) should have been received from the International Bureau.

INFORMATION DISCLOSURE STATEMENTS

The acknowledgment of the two previously filed Information Disclosure Statements and return of Examiner-initialed copies of applicants' Forms PTO-1449 are noted, with thanks. A further Information Disclosure Statement is filed herewith, together with the appropriate fee. The documents listed on the accompanying Form

PTO-1449 are submitted to support positions taken by applicants hereinbelow, where they are discussed in detail.

ELECTION/RESTRICTION

Applicants appreciate the Examiner's modification of the previous election/restriction requirement, such that SEQ ID NO: 4 and 5 are joined with elected SEQ ID NO: 6 for examination. Thus, Claims 1-11, 28-35 and 46-52 and SEQ ID NO: 4, 5 and 6 are being examined. New Claim 53 should also be examined as drawn to elected subject matter. Claims 36 and SEQ ID NOs: 1, 7, 8, 9, 16, 25 and 27 are deemed non-elected inventions and withdrawn from consideration.

In light of the subject matter examined herein, applicants have deleted non-elected SEQ ID NOs: 1, 7, 8, 9, 16, 25 and 27 from the examined claims, while reserving the right to file one or more divisional applications on the cancelled subject matter. In light of the amendment to Claim 28 to delete the non-elected sequence numbers, Claim 52 became redundant and has been cancelled.

Claim 36 has been cancelled as drawn to a non-elected invention, applicants reserving the right to file a divisional application drawn to the cancelled subject matter.

In view of the amendments made, it is believed that the claims are now in complete compliance with the restriction requirements.

INFORMALITIES

The disclosure has been objected to because Fig. 4 contains amino acid sequences while the brief description of Fig. 4 on page 28 does not contain the

sequence identifiers. The paragraph in question has been amended to insert the proper SEQUENCE ID NOs.

CLAIM OBJECTIONS

Claims 1-11, 28-35, 46 and 47 have been objected to for containing non-elected sequences. The foregoing claim amendments delete the non-elected sequences. Consequently, this objection has been overcome.

CLAIM REJECTIONS-- 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 7-11, 50 and 51 have been rejected under 35 U.S.C. § 112, first paragraph, as purportedly failing to comply with the enablement rejection and as failing to comply with the written description requirements. Applicants submit that all of Claims 7-11, 50 and 51 as well as new Claim 53 are free of these rejections.

First, applicants point out that Claims 7 and 10 have been amended hereinabove to specify that the skin conditions associated with a dysfunction of cell proliferation and/or differentiation (Claim 7) and a dermatological infection (Claim 10) are associated with corneodesmosin degradation. The remaining rejected claims depend from either Claim 7 or Claim 10 and thus also contain the added limitation. New Claim 53 is drawn to a method for degrading corneodesmosin in corneocytes comprising applying to corneocytes an effective corneodesmosin degrading amount of at least one polypeptide, the peptide sequence of which comprises at least one sequence selected from the group consisting of SEQ ID NO: 4, SEQ ID NO: 5 and SEQ ID NO: 6. Thus, all of Claims 7-11, 50, 51 and 53 require corneodesmosin degradation or treatment of a condition associated with corneodesmosin degradation; and corneodesmosin degradation is clearly shown in EXAMPLE XI of

the specification. The EXAMPLE XI data for SEQ ID NO: 6 is believed to enable one of ordinary skill to use SEQ ID NOs 4, 5 or 6 in the claimed methods, it being apparent to one of ordinary skill (and already acknowledged by the Examiner) that SEQ ID NOs: 4 and 5 comprise SEQ ID NO: 6.

As for identifying suitable homologs or mixtures derived from the proteolysis of the peptide, no more than routine experimentation would be involved in testing such materials in the procedures of EXAMPLE XI. However, applicants would be willing to also specify in Claims 7 and 10 that the homologs or mixtures derived from proteolysis of the peptide have corneodesmosin degrading activity, if the Examiner believes such an amendment would assist in overcoming the enablement and written description rejections.

Furthermore, with respect to the homologs, the term "homolog" is well-known to those of ordinary skill in the art. The meaning of this term is further specified in the as-filed specification. Thus, the specification sets forth on page 4, lines 4-12, that a homolog of a polypeptide or of a peptide sequence is intended to mean any polypeptide or peptide sequence having at least 85%, especially 90%, particularly 95% sequence homology and, where appropriate (as here), the same type of biological activity as the polypeptide or peptide sequence. This is further elaborated on page 4, line 15ff. See also, page 7, lines 7-19, where it is indicated that the homologs also encompass polypeptides having a similar hydropathic index, with one or more amino acid residues replaced by amino acid residues having a similar hydropathic index, without, however, changing the biological properties of the polypeptide. Consequently, if skilled person had any doubts about the meaning of

the term "homolog", he would be clearly and unambiguously informed by the teachings of the specification.

Still further, the instant specification contains ample information for performing the methods claimed herein. Specifically, EXAMPLE XI demonstrates a significant decrease in the percentage of residual corneodesmosin due to activated SASPase. In other words, it clearly proves the ability of an SASPase according to the invention to hydrolyze corneodesmosin. As noted on page 8, lines 28-30, of the specification, corneodesmosin is a marker of desquamation. In other words, EXAMPLE XI clearly proves the ability to hydrolyze corneodesmosin and thus to be effective for treating related disorders.

The application as filed discloses for the first time that the peptides according to the instant invention can be particularly useful in order to compensate for an imbalance in epidermal differentiation/proliferation (page 15, lines 15-18, page 17, lines 10-29; page 17, line 34 to page 18, line 18), and thus are useful in various dermatological disorders such as described at page 15, line 26 to page 18, line 9.

Moreover, the specification as filed clearly describes how such peptides are used in order to prepare cosmetic/pharmaceutical compositions (page 23, line 37 to page 38, line 24).

Consequently, the instant Claims 7 to 11, 50 and 51 are fully supported by the specification and the specification as filed contains all the information necessary to define and/or to perform the claimed subject matter.

Applicants also point out that the specification provides sufficient information in order to and perform the instant invention as claimed, independently of the teaching of Isogai *et al.* (US 6 979 557).

Still further, in order to prove that the link between corneodesmosin degradation and the conditions specified in Claims 7, 9, 10 and 11 was known to those skilled in the art at the time of the invention, applicants are submitting copies of a number of literature publications and abstracts, as well as a copy of a WO publication, all listed on the accompanying Form PTO-1449 and all published before applicants' priority date.

In view of the foregoing, it is clear that the skilled person, based on his knowledge of the art at the time of the invention and the information provided in the application as filed, would consider the written description to be sufficient and the claims to be enabled. Accordingly, withdrawal of the 35 U.S.C. § 112, first paragraph, rejections is believed to be in order and is earnestly solicited.

CLAIM REJECTIONS--35 U.S.C. § 112, SECOND PARAGRAPH

Claim 5-11, 35 and 49-51 have been rejected under 35 U.S.C. § 112, second paragraph, as purportedly being indefinite. The specific reasons given for this rejection are discussed below.

Thus, Claims 5 and 35 have been deemed indefinite because of the use of the term "a hydrophilic or hydropholic targeting agent." However, one of ordinary skill would know that this expression refers to an agent capable of signaling the molecule in a specific cell or tissue. Reconsideration and withdrawal of this portion of the rejection is therefore to be in order.

Claims 6-11 and 49-51 have been considered indefinite because of the use of the term "derived from". The Examiner has suggested the term "obtained from" and applicants have amended the claims accordingly. This portion of the rejection has thus been rendered moot.

Claims 7-11, 50 and 51 have been rejected as indefinite as to what outcome an effective amount of the polypeptide would produce. The expression utilized in these claims is not "an effective amount" but rather "a thus effective amount" which refers back to combating or treating the specified conditions. A person skilled in the art would easily understand that the amount is that which is required in order to obtain the expected effect, and that this amount depends upon a number of factors, including the specific polypeptide and the subject to which it is applied and can be readily obtained by routine experimentation. Nevertheless, in the interest of expediting prosecution, applicants would be willing to amend "a thus effective amount" to read "an effective corneodesmosin degrading amount" in these claims if the Examiner so requires to overcome this rejection.

In light of the foregoing, it is believed that this application is free of the record 35 U.S.C. § 112, second paragraph, rejection.

CLAIM REJECTIONS - 35 U.S.C. § 103

Claims 1, 2 and 28 have been rejected under 35 U.S.C. § 103(a) as purportedly being unpatentable over Isogai et al. U.S. Patent No. 6,979,557.

Claim 1 has been amended hereinabove by replacing the expression "the peptide sequence of which is represented wholly or partly by" to "the peptide sequence of which consist of". Claims 2 and 28 have been similarly amended so

that the phrase "a peptide sequence represented by" has been replaced with "a peptide sequence consisting of". The claims as so amended are both novel and unobvious over Isogai et al.

SEQ ID NO: 2323 according to Isogai *et al.* comprises over its 343 amino acids, 138 amino acids which have 100% homology with SEQ ID NO: 6 of instant invention, applicants' elected species, according to the sequence match provided by the Examiner. Thus, SEQ ID NO: 2323 of Isogai et al. comprises SEQ ID NO: 6 but it is not SEQ ID NO: 6. The amended claim language herein clearly excludes an amino acid sequence such as SEQ ID NO: 2323. An objective of Isogai *et al.* is to provide polynucleotides encoding novel polypeptides and the uses thereof (col. 2, lines 49-51). They might be useful for gene therapy, for example for treating cancers or inflammatory diseases (col. 32, lines 39-42), osteoporosis and ulcers (col. 139, line 25). The amino acid sequences are part of a clone which also has a nucleotide sequence; SEQ ID NO: 2323 is part of the clone NT2NE20005500 together with nucleotide SEQ ID NO: 684. However, this document is completely silent concerning the use of the polypeptides for the preparation of cosmetic/pharmaceutical compositions according to the instant invention, i.e. compositions of such a polypeptide in a physiologically acceptable medium. Moreover, no data in Isogai *et al.* demonstrate the therapeutic uses of such polypeptides, and even less the uses as claimed. Indeed, Isogia *et al.* is more dedicated to disclosing isolated amino acid sequences and corresponding polypeptides as such, as well as genetic engineering in order to obtain them, as shown in the Examples.

Moreover, even if one could glean from Isogai et al. a suggestion to place SEQ ID NO: 2323 in a pharmaceutical composition (a suggestion that applicants do not believe Isogai et al. make or that one of ordinary skill would derive therefrom), one has not arrived at the subject matter of amended Claims 1, 2 and 28, which do not allow for the presence of a peptide sequence such as SEQ ID NO: 2323.

In view of the foregoing, it is believed that all record rejections and objections have been overcome. Further, favorable action in the form of a Notice of Allowance is believed to be next in order and is earnestly solicited.

Respectfully submitted,

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